DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 26, 2015

Camber Spine Technologies
Mr. Daniel A. Pontecorvo
President & CEO
418 East Lancaster Avenue
Wayne, Pennsylvania 19087

Re: K143490
Trade/Device Name: VERTA Corpectomy Cage
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: December 8, 2014
Received: December 8, 2014

Dear Mr. Pontecorvo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143490

Device Name
VERTA Corpectomy Cage

Indications for Use *(Describe)*
The VERTA Corpectomy Cage is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The device is intended for use with bone graft and with supplemental fixation systems (such as anterior plating systems, or posterior screw systems) cleared for use in the spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Traditional 510k

as required by section 807.92(c).

VERTA Corpectomy Cage
K143490
Prepared 1/20/15

Submitter:	Camber Spine Technologies 418 E Lancaster Ave. Wayne, PA 19087
Contact Person	Dan Pontecorvo President Phone: 484-427-7060, Fax: (484) 318-8031 Email: dpontecorvo@cambermedtech.com
Trade Name	VERTA Corpectomy Cage
Common Name	Spinal Vertebral Body Replacement Device
Device Class	Class II
Classification Name and Number	Spinal intervertebral body fixation orthosis, 21 CFR 888.3060
Classification Panel:	Orthopedic
Product Code	MQP
Reason for 510k	New Device
Predicate Device	NIKO Corpectomy Spacer (K 072465)

Device Description	The VERTA Corpectomy Cage device is a vertebral body replacement device used to provide structural stability in skeletally mature individuals following Corpectomy or vertebrectomy. The VERTA System is comprised of implants of various heights, to fit the needs of individual patient anatomy. Geometrically, the implants are designed as a load bearing frame with a hollow center which are applied to the spine to provide long-term structural support throughout fusion and to help enhance the fusion rate. Serrations on the superior and inferior surfaces of the device are designed to grip the endplates of the adjacent vertebrae to resist expulsion. The VERTA System implants are made from PEEK radiolucent material with embedded tantalum x-ray markers as specified in ASTM F2026 and ASTM F560, respectively.
Indications for Use	The VERTA Corpectomy Cage is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The device is intended for use with bone graft and with supplemental fixation systems (such as anterior plating systems, or posterior screw systems) cleared for use in the spine.

Materials:	The implant is manufactured from Solvay Zeniva ZA-500 implant grade Polyetheretherketone **(**PEEK) (per ASTM2026). The accessories are manufactured from 17-4 Stainless Steel (per ASTM F899-11)

Statement of Technological Comparison	VERTA Corpectomy Cage and its predicate device have the same indications for use, similar design, technical characteristics, and test results. Both devices are manufactured using materials with a long history of use in orthopedic implants.

Nonclinical Test Summary	The following tests were performed to demonstrate that the VERTA Corpectomy Cage is substantially equivalent to other predicate device. • Static Compression Test per ASTM F2077 • Dynamic Compression Test per ASTM F2077 • Static Torsion Test per ASTM F2077 • Dynamic Torsion Test per ASTM F2077 • Subsidence Test per ASTM F2267 • Expulsion Test The results of these studies showed that the VERTA Cage met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.

Sterilization Information	
Implants	The Implant will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10^-6 per ISO 17665.
Instruments and Case	The instrument and case will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10^-6 per ISO 17665.

Conclusion	The VERTA Corpectomy Cage is substantially equivalent to its predicate device. This conclusion is based upon the fact the VERTA Cage and its predicate device have the same indications for use, have a similar design and technical characteristics, similar test results, and any differences do not raise question of safety and effectiveness.